Information on Bisphosphonates (marketed as Actonel, Actonel+Ca, Aredia, Boniva, Didronel, Fosamax, Fosamax+D, Reclast, Skelid, and Zometa)

FDA ALERT [1/7/2008] - FDA is highlighting the possibility of severe and sometimes incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates. Although severe musculoskeletal pain is included in the prescribing information for all bisphosphonates, the association between bisphosphonates and severe musculoskeletal pain may be overlooked by healthcare professionals, delaying diagnosis, prolonging pain and/or impairment, and necessitating the use of analgesics.

The severe musculoskeletal pain may occur within days, months, or years after starting a bisphosphonate. Some patients have reported complete relief of symptoms after discontinuing the bisphosphonate, whereas others have reported slow or incomplete resolution. The risk factors for and incidence of severe musculoskeletal pain associated with bisphosphonates are unknown.

This severe musculoskeletal pain is in contrast to the acute phase response characterized by fever, chills, bone pain, myalgias, and arthralgias that sometimes accompanies initial administration of intravenous bisphosphonates and may occur with initial exposure to once-weekly or once-monthly doses of oral bisphosphonates. The symptoms related to the acute phase response tend to resolve within several days with continued drug use.

Healthcare professionals should consider whether bisphosphonate use might be responsible for severe musculoskeletal pain in patients who present with these symptoms and consider temporary or permanent discontinuation of the drug.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this when additional information or analyses become available.

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